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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/914,659      | 01/28/2002  | Brian William James  |                     | 2344             |

7590

11/13/2003

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| EXAMINER |
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LILLING, HERBERT J

| ART UNIT | PAPER NUMBER |
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1651

DATE MAILED: 11/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/914,659             | JAMES ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | HERBERT J LILLING      | 1651                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-21 and 25-29 is/are pending in the application.
- 4a) Of the above claim(s) 25-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 25-29 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4310118 6/18/03
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

1. Receipt is acknowledged of the amended claims dated September 24, 2003.

2. Claims 1, 3-21 and 25-29 are pending in this application.

Claim 22 has been cancelled.

Claims 2 and 23-24 were previously cancelled.

3. Claims 25-29 stand from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. The amendments to the claims do not further limit the claims to the elected invention as drawn to the method of culturing mycobacteria. The further reaction is considered to be a separate and patentably distinct invention.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 7-10 and 14-21 are rejected under 35 U.S.C. 102(b) **as anticipated** by Stinson et al "Interaction of Tween 80 Detergent with Mycobacteria in Synthetic Medium" Amer. Rev. Resp.Dis. 104: (1971) pgs 717-727.

Stinson et al teaches the method of culturing mycobacteria in the presence of Tween 80-which is a known detergent- at a concentration that includes 2% in the presence of L-asparagine, glycerol and trace elements, see page 718, Materials and Methods as well as incubating at the same range, see page 718 second column under "Cultivation". The cultivation was also agitated, see "Cultivation". The pH employed by Stinson et al was also within the range see examples

**or, in the alternative,**

for Claims 6 and 11-13 are under **35 U.S.C. 103(a)** as obvious over:  
by Stinson et al "Interaction of Tween 80 Detergent with Mycobacteria in Synthetic Medium" Amer. Rev. Resp. 104: (1971) pgs 717-727 further in view of Wayne "Amer. Rev. Resp.Dis "114 (1976) pgs 807-811 or Thornton, U.S. 6,004,771 "Method for processing mycobacteria".

It would have been prima facie obvious to substitute one Mycobacteria for another especially the *M.tuberculosis* for the *M. avium* in view of the disclosure by Stinson on page 722 second column or further in view of Thornton who teaches the alternative. The adjustment of the conditions with respect to the culturing by continuous procedure, dilution rate and the amount of dissolved oxygen as well as the amounts of detergent or the medium for the culturing would have been prima facie in view of the teachings of Stinson further in view of Wayne or Thornton absent unexpected or unobvious process conditions.

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5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

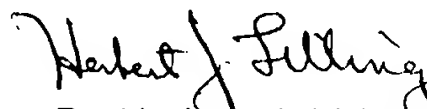
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for asparagine as a mitogen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and practice the invention commensurate in scope with this claim. Mitogen is usually defined as a polypeptide and not an amino acid per se.

6. **No claim is allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is (703) 308-2034** and **Fax Number** is for applications **Before Final** (703) 872-9306 and **After Final** for applications is 703-872-9307 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL  
(703) 308-2034  
Art Unit **1651**  
November 12, 2003

  
Dr. Herbert J. Lilling  
Primary Examiner  
Group 1600 Art Unit 1651